Since Last We Met.....

An Update of the last 12 months of activities regarding the interaction of Medical Devices and Security Systems.

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While it still appears that ambulatory medical device EMI from security systems does not pose a major public health issue at this time, FDA continues to be concerned about the potential for adverse patient interactions.

FDA continues to believe that a comprehensive study of the public health risk of medical device EMI with security systems is still needed, and that such a study must include a fully representative sample of security systems and ambulatory medical devices.

Medical Devices

- Implanted Pulse Generators (IPG's),
- Implanted Cardioverter Defibrillators (ICD's),
- Spinal cord stimulators,
- and infusion pumps.

Objective

- Provide background on laboratory research programs and activities related to electromagnetic interference from electronic article surveillance systems (EASS's) and metal detectors (MD's).
- Discuss *in vitro* published studies.

What are EASS's and MD's?

- Devices that emit electromagnetic fields that cause anti-theft tags or metal passing through the systems to emit a detectable electromagnetic signal.
- MD systems include walk-through as well as hand-held detectors.
- People and products are exposed.

Concerns

- Medical Device Reporting system continues to receive reports of device interactions.
- Two clinical studies published since last year show that electromagnetic fields emitted from EASS's can interfere with IPG's and ICD's.

Health Canada *In Vitro* Study

Mode	EASS			WTMD		HHMD
	CW	PM	Swept	CW	PM	CW
Fixed Rate Pacing	52% (11/21) 14%* (3/21)	95% (20/21) 38%* (8/21)	0% (0/21)			
External Simulated EKG	52% (11/21)	95% (20/21)				
Not Specified				15% (2/13)	31% (4/13)	0% (0/13)

*Decreased rate of pacing

References for *In Vitro* EAS Testing

- Tan, K.;Hinberg, I.: A Laboratory Study of Electromagnetic Interference Effects from Security Systems in Implantable Cardiac Pacemakers. URSI, Toronto, Canada, August 1999.

Data from Studies Should:

- Be supportive of standards development
- Include distances of interaction
- Document exposure required to cause interactions

Data from Studies Should:

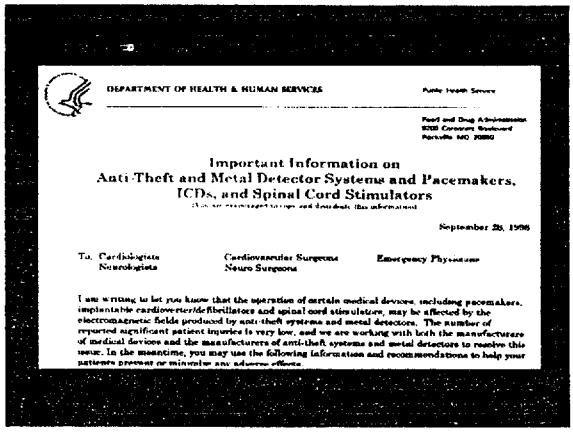
- Document patient or device orientation with the security system when interactions occur.
- Be a complete representative sample of the security systems and medical device technologies in use.

FDA Activities

- AAMI Pacemaker committee EMC Task Force draft of PC69 -- "Active implantable medical devices electromagnetic compatibility (EMC) test protocol for implantable cardiac pacemakers and implantable cardioverter defibrillators."
- Chaired by Mitchell Shein, CDRH (our next speaker)
- Has begun work on 0-30MHz EMC Section

FDA Activities

- AAMI sessions on medical device EMC with EASS in Boston, July 1999
- URSI session in Toronto, August 1999
- Joined ASTM F12 Security Systems Committee
- CDRH Letter to EASS and Metal Detector Industry encouraging research



DEPARTMENT OF HEALTH & HUMAN SERVICES

Important Information on
Anti-Theft and Metal Detector Systems and Pacemakers, ICDs, and Spinal Cord Stimulators

September 28, 1998

To: Cardiologists Neurologists | Cardiovascular Surgeons Neuro Surgeons | Emergency Physicians

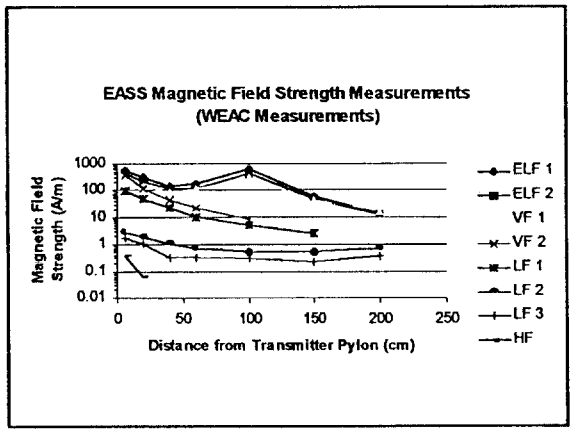
I am writing to let you know that the operation of certain medical devices, including pacemakers, implantable cardioverter/defibrillators and spinal cord stimulators, may be affected by the electromagnetic fields produced by anti-theft systems and metal detectors. The number of reported significant patient injuries is very low, and we are working with both the manufacturers of medical devices and the manufacturers of anti-theft systems and metal detectors to resolve this issue. In the meantime, you may use the following information and recommendations to help your patients prevent or minimize any adverse effects.

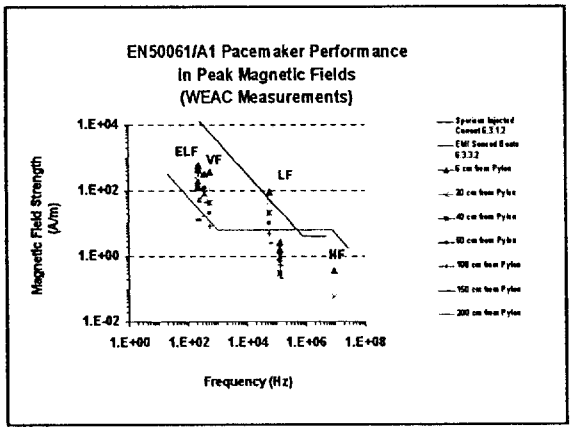
FDA Activities: Publications

- Witters, D.: FDA Concerns About Medical Device Electromagnetic Interference with Electronic security Systems. MDDI: October 1999

FDA Activities: Publications

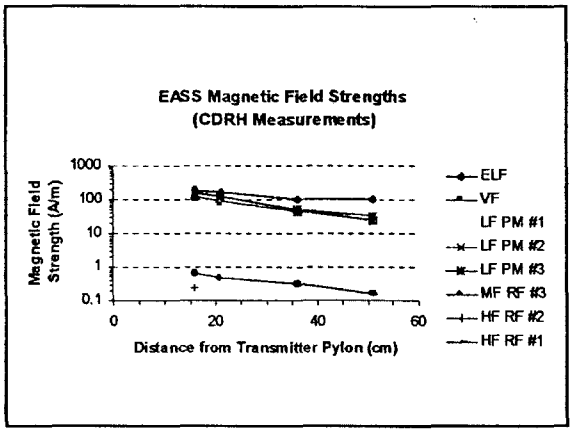
- Harris, C.; et. al.: Electromangetic Field Strength Levels Surrounding Electronic Article Surveillance (EAS) Systems. Health Physics, in press.

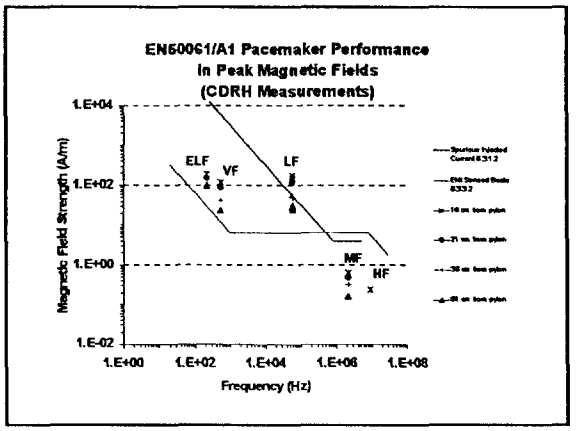




FDA Activities: Publications

- Casamento, J.: Engineering Characterization of Common Electronic Article Surveillance Systems Electromagnetic Fields. Compliance Engineering, Sept/Oct Issue





FDA Activities

- FAA, NIST, and FDA will work together to analyze metal detector interactions with medical devices.
- Walk-through metal detectors (WTMD)
- Hand-held metal detectors (HHMD)
- Electromagnetic field measurements and characterization.
- Develop standardized test methods for certain medical devices.

Conclusion

- While it still appears that ambulatory medical device EMI from security systems does not pose a major public health issue at this time, FDA continues to be concerned about the potential for adverse patient interactions.
- FDA continues to believe that a comprehensive study of the public health risk of medical device EMI with security systems is still needed, and that such a study must include a fully representative sample of security systems and ambulatory medical devices.

Data from Studies Should:

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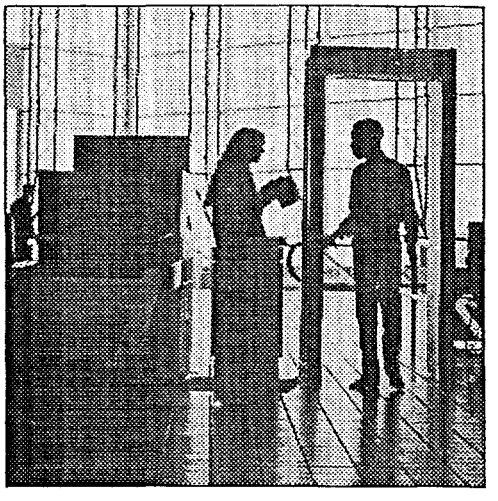
Characterizing Electromagnetic Fields of Common Electronic Article Surveillance Systems

JON P. CASAMENTO



During the past decade, the U.S. Food and Drug Administration (FDA) has received more than 28 medical device reporting incidents of adverse interactions between medical devices and electronic article surveillance (EAS) systems, metal detectors, and security systems.[1] Several case reports and four peer-reviewed studies document adverse interactions between EAS systems and implanted pacemakers, implanted automatic cardiac defibrillators, implanted neurostimulators, and other ambulatory medical devices.[2,3,4–7] Anecdotal reports and many newspaper articles suggest that many more device interactions have occurred and gone unreported.

Each year millions of people enter establishments protected by EAS systems. Because more people are using electronic implants and ambulatory medical devices, adverse interactions with EAS systems are of increasing concern. FDA conducted a study to provide data to characterize electromagnetic fields generated by EAS systems. The data presented in the study are being used for susceptibility testing of various implanted cardiac devices and other ambulatory medical devices to magnetic fields emitted from EAS systems.

Systems Tested

FDA's Center for Devices and Radiological Health (CDRH) identified EAS systems in common use and collected samples of the most popular technologies used in the United States. These included extremely low frequency and voice-frequency (both continuous-wave magnetic), low-frequency pulsed magnetic, and medium-frequency and high-frequency swept radio-frequency systems. An EAS system installer (Sentec EAS Corp.; Deerfield Beach, FL) and an EAS system manufacturer (Checkpoint Systems Inc.; Thorofare, NJ) loaned sample systems to CDRH for the study. The seven sample systems, including one duplicate, were from three different manufacturers: Sensormatic Electronics Corp. (Boca Raton, FL); Knogo North America (Hauppauge, NY); and Checkpoint Systems Inc.

Testing Instruments and Methods

Each EAS system was mounted on a simple wooden platform. The purpose of the platform was to fix the separation distances between the transmitter and receiver pylons to separation distances found in the typical installation for each type of system. A magnetic loop antenna connected to a Hewlett-Packard (Palo Alto, CA) Model 8560E spectrum analyzer and a Tektronix Inc. (Portland, OR) Model TDS 380 oscilloscope measured the frequency of operation, modulation type, and duty cycle of each EAS system.

The spatial magnetic flux density distributions were mapped using a scanning system capable of positioning a probe anywhere in a volume measuring 2 m wide × 2 m deep × 1 m high. The software to control the scanning system was developed by Sonix Inc. (Springfield, VA). Data were recorded via a Datel Inc. (Mansfield, MA) PC414A high-speed analog input board with 12/14-bit analog-to-digital resolution. The three-axis scanning system was bolted to the ceiling of a shielded room. The z-axis structure (representing up and down scanning) was constructed of nonconducting materials that are minimally perturbing to electromagnetic fields.

Different electromagnetic field measurement systems were used for different frequency ranges (see Table I). All except one were three-axis (isotropic) probes that measured the total magnetic field at a given point. A single-axis Deno electric field measurements (EFM) (West Stockbridge, MA) Model 116-3-60-0367 magnetic field probe was used for the extremely low

Photo by MASON MORFIT/FPG

frequency field mapping (219–535 Hz). The extremely low frequency magnetic fields were mapped in three separate scans for each plane. In each scan, the Deno magnetic field probe was oriented along a different orthogonal axis. At each point, the data were then combined using the square root of the sum of the squares in each of the three orthogonal field components. Extremely low frequency and very low frequency magnetic fields were also measured using a Holaday Industuries Inc. (Eden Prairie, MN) Model HI-3627 extremely low frequency magnetic field meter (5 Hz–2 kHz).

The voice-frequency magnetic fields were mapped using a Wandell and Goltermann (Research Triangle Park, NC) Model EFA-2 (5 Hz–30 kHz) field analyzer that can make isotropic measurements. Low-frequency pulsed magnetic fields were mapped using a Holaday Industries Inc. Model HI-3637 very low frequency (2–400 kHz) isotropic magnetic field meter. The medium- and high-frequency swept radio-frequency magnetic fields were mapped using an HI-4433-LFH broadband (0.3–10 MHz) magnetic field probe. The electric fields were mapped using an HI-4433-HSE (0.5 MHz–1.5 GHz) isotropic electric field probe. Prior to making these magnetic field measurements, the probes were calibrated using an EMCO (Austin, TX) Helmholtz coil, driven by a Hewlett-Packard Model 33120A function/arbitrary waveform generator connected to an ADCOM (East Brunswick, NJ) GFA-555II high-current power amplifier. For the low-frequency range (30–300 kHz) and higher-frequency ranges, the arbitrary waveform generator was connected directly to the Helmholtz coil. Current to the Helmholtz coil was monitored across a precision 1% 20-W 0.866-Ω resistor with a Fluke (Everett, WA) Model 87 True rms multimeter, a Keithley Model 197 autoranging microvolt digital multimeter, or a Tektronix Model TDS 380 digital real-time oscilloscope, depending upon the frequencies being calibrated.

The low-frequency to high-frequency magnetic field probe accuracy was verified by using spot measurements with a single-loop antenna and the HP-8560E spectrum analyzer. A single turn loop of area 21.5 cm² was made from a section of 0.325-in. (8.26 mm) diam 50-Ω semirigid cable measuring 86 cm from the center of the loop to the end of the connector. The outer copper jacket of the loop is cut circumferentially around the portion of the cable jacket centered on the section of the loop farthest from the main shaft leading to the N-type connector to cancel electric field–induced currents. This loop was placed in the magnetic field at the same location as the low-frequency and high-frequency magnetic field probes; it was rotated to achieve the maximum reading on the spectrum analyzer. The calculated field strength from the single turn loop was then compared with the measured field strength from the HI-4433-LFH broadband isotropic magnetic field probe. When the measurements from the two instruments were within ±1.5 dB, they were considered to agree.

Instrument	Magnetic/Electric Field Type	Frequency Range	Minimum Sensitivity
Deno EFM 116-3-60-367	Single-axis magnetic	219 Hz* and 535 Hz*	0.13 μT
Wandell and Goltermann EFA-2 field analyzer	Three-axis magnetic	5 Hz–30 kHz*	0.04 μT
Holaday Industries HI-3627 three-axis magnetic field meter	Three-axis magnetic	5 Hz–2 kHz*	0.02 μT
Holaday Industries HI-3637 three-axis magnetic field meter	Three-axis magnetic	2–400 kHz*	0.004 μT
Holaday Industries HI-4433-LFH broadband isotropic magnetic field probe	Three-axis magnetic	0.3–10.0 MHz	1.26 μT
Holaday Industries HI-4433-HSE broadband isotropic electric field probe	Three-axis electric	0.5 MHz–1.5 GHz	0.3 V/m

*Calibrated using an EMCO 6402 Helmholtz coil at the specific frequencies measured.

Table I. Measurement instruments used for EM field mapping of EAS systems.

A scanning protocol specified that electromagnetic measurements would be made in two horizontal planes and three vertical planes around the transmitter pylon resulting in five data sets. Measurements were made at two heights in the horizontal plane (see Figure 1) for each EAS system. An electromagnetic field map was made at a height of 130 cm and at the height of the maximum flux density for each EAS system (as determined by a scan of the vertical normal plane). Vertical measurements were made in three different planes. Two vertical-plane measures were performed, each parallel with the face of the EAS system transmitter pylon. The planes were located 6 and 36 cm from the transmitter pylon face. The vertical planes were 100 cm high starting 55 cm from the base of the transmitter pylon. The third vertical plane was normal to and centered on the face of the transmitter pylon (see Figure 3). The nearest edge of this plane was 6 cm away from the pylon of the EAS system.

Laboratory Research Results

Figure 2 shows an example plot for the horizontal plane 130 cm from the floor. Table II provides a summary for the eight systems of the maximum magnetic flux density measured at a single point 36 cm from the EAS system transmitter pylon face at a height of 130 cm from the ground, along the centerline of

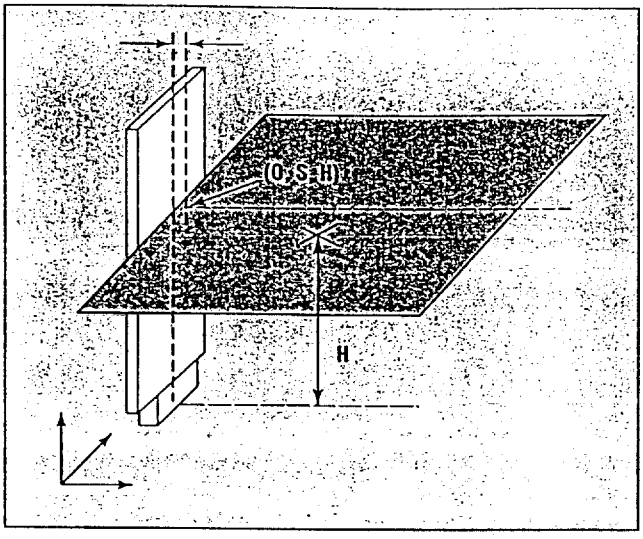


Figure 1. The horizontal plane, normal to the face of the EAS system transmitter pylon. H = the height from the base of the EAS system pylon, 130 cm and x cm, where x = the height of the maximum field strength. S is 6 cm from the transmitter pylon face.

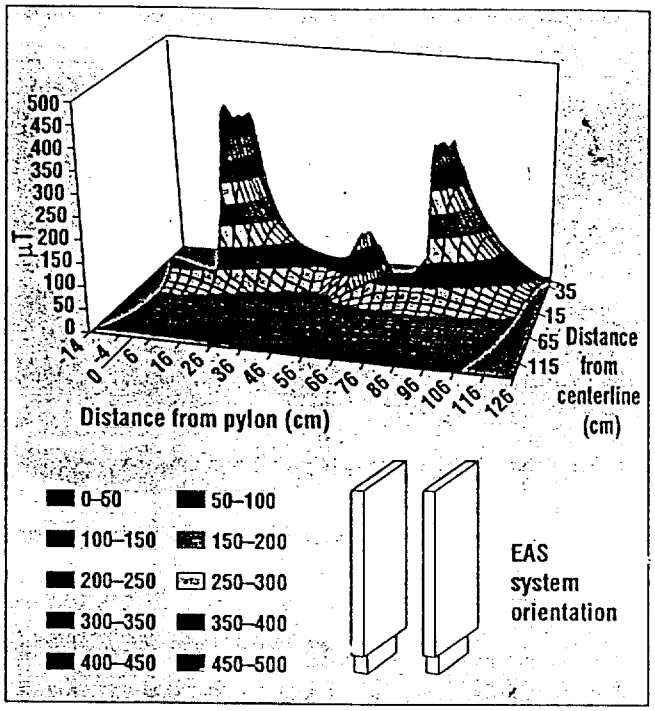


Figure 2. The magnetic EAS system #1 with both system pylons transmitting magnetic fields. The distances noted are with reference to the inside face of one pylon (left side) as indicated by the distance from pylon axis.

the pylon. The distance from the floor roughly approximates that of an implanted pacemaker in a standing adult. The horizontal distance from the transmitter pylon was chosen to minimize mutual inductance between the magnetic field probe and the transmitter pylon. Also, at distances greater than three probe diameters, the error between the idealized point measurement reported and the isotropic volume measurement of an ideal magnetic field probe is less than 0.04 dB (1%). This determination was made by a simple spreadsheet model of a field gradient comparing point measurements to an idealized measurement probe surface.

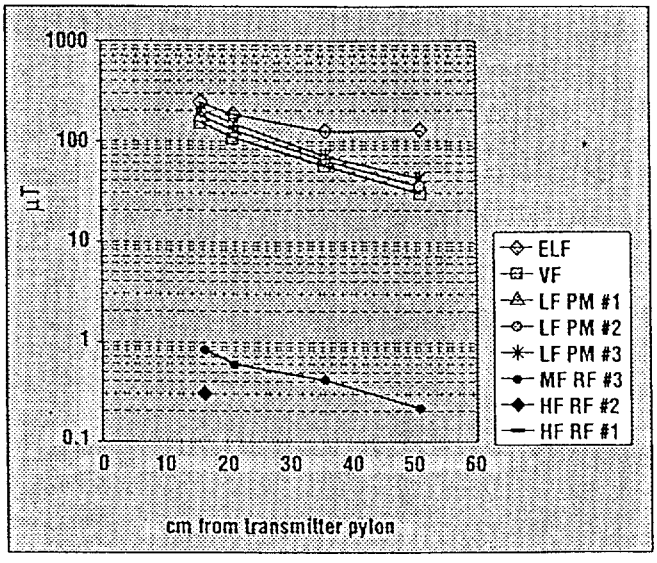


Figure 3. Magnetic field strengths for all EAS systems in the horizontal plane 130 cm from the floor.

Analysis and Discussion

Data are presented as peak magnetic flux density. This format was chosen so that the magnitude of the magnetic flux density emitted from these EAS systems could be compared. Time-varying magnetic fields (dB/dt) induce voltages in tissues and medical device leads that can be readily calculated from peak magnetic flux density, frequency, and modulation. Using these calculations, medical device designers can determine if interactions are likely when the device is exposed to given magnetic flux densities and waveforms.

Converting continuous-wave modulation measurements from instruments reporting true root-mean-squared (rms) values is straightforward. Data for the pulsed EAS systems required special analysis because of the nature of the instruments used. The magnetic flux densities displayed by the Holaday Industries isotropic field instruments for extremely low frequency, voice-frequency, very low frequency, and low-frequency magnetic fields are generated by true rms converter-integrated circuits. The true rms values from the circuits are combined from each of the three orthogonal magnetic field sensors through

EAS System	Frequency	Modulation	Magnetic Field Strength (μT)	Pylon Separation (cm)
Magnetic #1 (ELF)	215 Hz	CW	122	183
Magnetic #2 (VF)	535 Hz	CW	72	732
Pulsed magnetic #1 (LF)	58 kHz	Pulsed	64.9	182.9
Pulsed magnetic #2 (LF)	58 kHz	Pulsed	62.2	182.9
Pulsed magnetic #3 (LF)	58 kHz	Pulsed	61.2	274.3
Swept RF #1 (HF)	7.2–9 MHz	FM	<1.0	914
Swept RF #2 (HF)	7.6–8.9 MHz	FM	<1.0	914
Swept RF #3 (MF)	1.8–2.1 MHz	FM	1.0	182.9

*36 cm from transmitter pylon centered 130 cm from floor; †10% duty cycle, 1.66 ms ON, 16.6 ms interpulse interval; ‡12 ms/sweep, ±10% of center frequency. ELF = extremely low frequency, VF = voice frequency, LF = low frequency, HF = high frequency, and MF = medium frequency.

Table II. Summary of EAS system and field strengths.

vector addition to produce the resultant magnetic field magnitude displayed by the instrument. In our study, we converted the rms values (B_{rms}) for magnetic flux densities to peak measurements for the gated low-frequency sinusoid as shown in the following list using the definition of rms as given in equation (1).

$$B_{rms} = \sqrt{\frac{1}{T}\int_0^T f^2(t)dt} \qquad (1)$$

Substituting the equation of a sinusoid for f(t) yields equation (2), where $\omega = 2\pi f$, f = the frequency of the sinusoid, T = the period of the gated sinusoid, and B_0 = the peak magnetic flux density.

$$B_{rms} = \sqrt{\frac{1}{T}\int_0^{T/10}[B_0 Sin(\omega t)]^2 dt} + \sqrt{\frac{1}{T}\int_{T/10}^{T}[B_0 Sin(\omega t)]^2 dt} \qquad (2)$$

The integral is evaluated from $0 \le t \le T/10$, where T/10 is the duty cycle of the gated sinusoid from the EAS units we calculated. Since the amplitude of the gated sinusoid is zero from $T/10 \le t \le T$, the second term in equation (2) is equal to zero. The simplified solution for the integral is shown below in equation (3).

$$B_{rms} = B_0\sqrt{\frac{1}{20} - \frac{Sin\left[2\omega\left(\frac{T}{10}\right)\right]}{4\omega T}} \qquad (3)$$

For $\omega >> 1/T$, equation (3) can be approximated as

$$B_{rms} \approx \frac{B_0}{\sqrt{20}} \qquad (4)$$

Peak Magnetic Flux Density. Figure 3 is a summary of the peak magnetic flux densities measured in the horizontal plane 130 cm from the floor (as shown in Figure 1). The closest measurements shown in Figure 3 are 15 cm from the transmitter face. Data measured closer than this distance are likely to contain large errors due to mutual inductance between the coils of the EAS system and the magnetic field instrument. The EAS system technologies measured indicate that the magnetic flux densities are highest for the extremely low frequency, voice-frequency, and low-frequency systems. The radio-frequency systems (medium frequency and high frequency) had weaker magnetic flux densities. The extremely low frequency system that we measured had two transmitting pylons. In this system, the exposure to the magnetic fields remains relatively higher anywhere between the pylons than was measured between the single-transmitter pylon systems. Table II shows a numerical summary of the flux densities measured 36 cm from each of the transmitter pylons at a single point on the centerline of the EAS systems.

System Installation Specifications. Each EAS system manufacturer specifies the nominal environmental conditions in which their units should be installed. Because most of the systems studied were installed by a third party and were acquired as used systems, some of the units may not have flux densities representative of a system installed by the manufacturer's representatives. However, since these EAS systems are available on the market, the magnetic flux densities measured would represent exposures that may be encountered by the public. Subsequent transmitter coil current measurements indicated that two of the low-frequency systems (PM #1 and PM #2) produced magnetic fields more than 10% stronger than the manufacturer reported as nominal at the specified supply voltage. These units also have unregulated power supplies. The building power supplied to these units was not regulated during testing. The typical supply voltage to the systems during our testing was 126 V ac, which was 16 V ac (15%) more than the manufacturer's designed nominal ac voltage of 110 V ac. These two factors combine to produce reported magnetic flux densities that may be stronger than nominal for many units installed by the manufacturer and operated at the nominal power line voltages (110 V ac).

EAS System	Frequency	Modulation	Flux Density (S = 40 cm, H = 130 cm (μT)		Difference (dB)
			CDRH	WEAC	
Magnetic #1 (ELF)	219 Hz	CW	117.9	*167.4 (H1)***	3.0
Magnetic #1 (ELF)	219 Hz	CW	117.9	141.6 (H2)***	1.6
Magnetic #2 (VF)	535 Hz	CW	136	130.2	0.4
Pulsed magnetic #3 (LF)	58 kHz	Pulsed	38.5	27.1	3.0
Swept RF #2 (HF)*	8 MHz	Swept	0.3	8.5 (R1)***	29.9
Swept RF #2 (HF)	8 MHz	Swept	0.3	1.25 (R2)***	13.2
Swept RF #2 (HF)	8 MHz	Swept	0.3	0.4 (R3)***	3.3
Electric Field			V/m	V/m	
Swept RF #1 (HF)	8 MHz	Swept	0.16	**	16.0
Swept RF #1 (HF)	8 MHz	Swept	0.16	0.14 (R3)***	0.97
Swept RF #2 (HF)	8 MHz	Swept	1.0	0.14 (R3)***	17.0

*CDRH RF #1 magnetic flux density could not be measured at this distance with the HI-4433-LFH.
**Comparison between CDRH RF #1 and CDRH RF #2.
***WEAC system identifiers for units operating at similar frequencies. R1, R2, and R3 are library systems. H1 and H2 are retail systems.

Table III. Comparison of CDRH and WEAC data.

Field Tests of EAS Systems

FDA's Winchester Engineering and Analytical Center (WEAC) measured a number of EAS systems in use in retail stores and libraries in and around the greater Boston area.[8] Results of this study were compared with measurements reported in this paper for similar systems based on the EAS system emission frequency (Table III). WEAC measured two extremely low frequency systems in music stores. The separation distances between EAS system pylons for these units were greater than the pylon separation distances that were recommended for the extremely low frequency EAS system installed in the CDRH laboratory. The flux densities measured were generally higher for the field systems than for the unit measured in the laboratory by 3 and 1.6 dB respectively at a horizontal distance of 40 cm from the transmitter pylon and 130 cm above the floor. When the maximum values of the measurements made in the field and in the laboratory are normalized to one and compared, the data show differences of –1.2 and –0.4 dB respectively at 40 cm from the transmitter pylon and 130 cm from the floor.

Comparison of flux densities for voice-frequency EAS systems at 40 cm from the transmitter pylon and 130 cm from the floor showed measurement differences of 0.2 dB. Flux densities for low-frequency EAS systems at 40 cm from the transmitter pylon and 130 cm from the floor showed measurement differences of 3 dB; normalized data show a difference of 2.1 dB. The radio-frequency EAS systems have relatively weak magnetic fields, and, therefore, the instruments used by both groups were not able to measure the magnetic fields for the laboratory EAS systems at distances of 40 cm or greater. The radio-frequency systems measured by WEAC were library systems.

Differences between electromagnetic flux densities measured in the laboratory by CDRH and field measurements by WEAC would be expected. The make and model numbers of some of the systems measured by WEAC were not the same as the models measured in the laboratory. Differences in commercial ac power levels supplied to the systems and the presence of conductive and magnetic materials in proximity to the systems or the fields being measured could change the electromagnetic field levels and patterns generated by the systems (Table III). Measurements made where the flux densities are weak and where flux densities are close to the minimum sensitivity of the measurement instrument are subject to greater measurement error. Under these conditions, small perturbations will indicate larger differences in electromagnetic field measurements. Probe positional differences can also significantly affect the repeatability of measurements, particularly for those made close to the source. Here the flux densities are changing rapidly with distance. While efforts can be made to control these variables in the laboratory, they are very difficult to control during on-site measurements.

Conclusion

FDA studied eight EAS systems representing seven different models from three manufacturers. The operating frequencies of these units varied from about 200 Hz to about 10 MHz. Spatial maps of electromagnetic fields indicate that lower frequency systems generally have stronger magnetic fields than the high frequency systems. Magnetic fields also fall off rapidly as distance increases from the transmitting

coil. Measurements indicate that systems installed in retail stores and libraries may have flux densities that vary within ±3 dB of the laboratory measurements. Magnetic fields emitted from individual EAS units of the same model may vary.

There have been a number of reports of implanted and other ambulatory electronic medical devices interacting with the electromagnetic fields emitted from EAS systems. The information provided in this paper may be useful in studying such EMI and in helping engineers employ design techniques to minimize the vulnerability of implanted equipment.

Acknowledgments

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FDA Concerns About Medical Device EMI with Electronic Security Systems

In view of the variable and complex nature of EMI disruptions of medical devices, a cautious approach toward interference with other devices is warranted.

Donald Witters

Several recent reports have raised concerns about the potential risks for medical device users from electromagnetic interference (EMI) with the normal operation of medical devices by certain electronic security systems, including electronic article surveillance systems (EASS) and metal detectors. While the number of reported significant patient injuries from EMI with EASS and metal detectors is low, the information to date suggests that the electromagnetic energy emissions from EASS and metal detectors can interact with some critical medical devices.

Although the full extent of the interactions on specific medical devices is not known, there does not appear to be a major public health concern at this time. However, with the increasing complexity and portability of medical devices and the proliferation of EASS and metal detectors, the FDA's Center for Devices and Radiological Health (CDRH) has become concerned about the potential for EMI between these technologies and medical devices.

EASS and antitheft systems have become widely used in commercial establishments, and metal detectors are used for security in many buildings. Both of these kinds of electronic security systems emit electromagnetic energy to detect the presence of a special tag (EASS) or metallic materials (metal detectors). With the limited information currently available, CDRH has sought to engage medical device and security system manufacturers in ways that will address medical device user concerns while not un-

Illustration by NAME HERE

duly alarming device users or clinicians. (Figure 1.)

CDRH has taken an active role in calling attention to the potential risk to medical device users. The agency has performed laboratory research, raised public awareness, and provided a scientific forum to address these concerns. For example, on September 24, 1998, CDRH organized a discussion of its concerns about medical device EMI with EASS and metal detectors before the Technical Electronic Product Radiation Safety Standard Committee (TEPRSSC), an advisory committee established under the Radiation Control for Health and Safety Act of 1968. At this public meeting, CDRH scientists and a physician outlined CDRH's current information regarding these EMI interactions, including: an analysis of medical device reporting (MDR) network reports, a review of the technical literature, and the results of laboratory measurements performed by CDRH. Manufacturers of medical devices and EASS and metal detectors also presented their perspectives. In addition, several leading cardiologists presented their clinical impressions of the significance of medical device EMI with these systems.

As a result of the information presented, the TEPRSSC agreed with CDRH's plan to inform physicians about the potential for EMI from EASS and metal detectors.[1] Further, CDRH is working with the Association for the Advancement of Medical Instrumentation (AAMI) and the American Society for Testing and Materials (ASTM) to help formulate standards for medical devices (e.g., cardiac pacemakers and implantable cardiac defibrillators [ICDs]) and metal detector systems, respectively, to address EMI with both the medical devices and the security system emitters.

CDRH has analyzed more than 50 MDR reports dating back to 1987 for suspected incidents of security system EMI with medical devices. Several reports contain information about serious patient consequences related to EMI with EASS, metal detector systems, or security systems. The largest group of reports (33) involved moderate to severe patient consequences from EMI with cardiac pacemakers and ICD devices. Twenty reports involved EMI with implanted spinal cord stimulators used for relief of chronic pain. Most of these ad-

verse interactions were considered as moderate in level of severity. Examples of the most concerning MDR reports for several medical devices are summarized below.

- A pacemaker patient reportedly lost consciousness when standing for approximately 2 minutes near an EASS tower (MDR 573141).
- In four separate incident reports, patient ICDs were reprogrammed into the inactive mode after the patient passed through, or was hand-scanned by, a metal detector (MDR 806666, MDR 858835, MDR 212215 1997 00106, MDR 2124215 1997 00229).
- A pacemaker patient's pulse dropped from 70 down to 31 beats/min while being interrogated with a metal detector in an airport (MDR 358472).
- An inappropriate firing of an ICD occurred when a patient leaned against an EASS pylon in a grocery store (MDR MW1006883).
- An overinfusion of drugs occurred, which later required dialysis to remove the excess drug, after the patient had passed through a metal detector; the device manufacturer reported that the infusion pump was functioning properly when tested after the incident (MDR 232087).
- While near a security system, an implanted spinal cord stimulator patient experienced a strong shock, followed by sporadic shocks that resulted in unconsciousness and hospitalization (MDR 6000033199700079).

While the numbers of MDR reports may be relatively small, the types of interactions reported serve as a valuable indicator of potential problems. In many cases, manifestations of EMI effects appear to be only intermittent or momentary. As a result, it can be difficult to associate the adverse interaction with a specific interference phenomenon or known source of EMI. With interference from an EASS, for example, patients may experience some device interaction while they are within the EASS field. The noticeable effects of the EMI may quickly diminish once the patient has exited the system. In many reported EMI cases, the effects appear to result in immediate patient symptoms such as a change in heart rate or overstimulation to nerve tissue. However, in some cases a

patient might not immediately associate the adverse interaction with the exposure, yet the possibility of suffering serious consequences remains (as in the cases of drug overinfusion or reversion of an ICD to monitor mode mentioned above). Unlike interference from medical device users' personal hand-held transmitters, such as cellular phones (where the user is aware of the EMI source and, for the most part, is voluntarily exposed), security systems are widespread and deliberately placed in locations that are difficult to avoid. In some cases, an EASS may be hidden and patients may not even be aware of the electromagnetic exposure. In view of the variable and complex nature of EMI disruptions of medical devices, a cautious approach toward addressing concerns for medical device safety and effectiveness is warranted.

REPORTS IN TECHNICAL AND MEDICAL LITERATURE

Potential EMI with cardiac pacemakers from a variety of electromagnetic sources is widely known in the clinical community and is addressed by manufacturers in device design, labeling, and education. However, only a few studies have targeted EMI from EASS, and even fewer have addressed metal detector systems. Large multicenter studies, like those performed for other EMI concerns such as cellular telephones, seem to be absent.[2] Nevertheless, there have been a few case studies have been reported in the medical literature that involve EMI with ICDs and spinal cord stimulators. For example, McIvor reported on one such incident in which an ICD patient leaned up against an EAS system and experienced a defibrillation shock.[3] Mathew et al. have also reported an incident linking an ICD output shock with an EASS.[4] In addition to the ICD reports, Eisenberg and Waisbrod reported on a serious injury to a patient with an implanted spinal cord stimulator exposed to an EASS.[5]

McIvor also performed a study with 25 ICD patients and 50 pacemaker patients that were exposed to six different EAS systems in a systematic approach.[6] Although no interactions were seen with the ICD patients in this study, nearly all of the pacemaker patients experienced some interaction with one or more of the

EASS. The interactions reported varied depending upon the pacemaker, the testing protocol, and the type of EASS. Exposure to one type of EASS (pulsed magnetic) revealed signs of EMI in 48 out of 50 pacemaker patients, with some patients experiencing dizziness. McIvor characterized the interactions in four main types, some with significant clinical implications. However, none of the pacemakers or ICDs in this study were reprogrammed by the interactions reported by McIvor.

Wilke has also reported on interference with implanted pacemakers by EASS.[7] His study indicated that the pacemakers in 7 out of 53 patients experienced some type of interference with an EASS that had higher electromagnetic fields associated with it. As a result of this study, Wilke suggests that pacemaker patients should avoid coming close to an EASS for any length of time.

In addition to the studies and reports with patients, there are several reports of work performed in vitro using ICDs and pacemakers.[8-10] The results of these studies suggest that lower-frequency and pulsed-type EASS might interfere more with implanted medical devices than the swept radio-frequency (RF) or microwave systems (Table I). Unfortunately, there is a dearth of such studies for metal detectors.

Taken as a whole, some common threads emerge from the published work that are consistent with CDRH's experience with medical device EMI. For instance, many medical devices are designed to sense and react with physiological signals, which are usually low frequency (e.g., from 0.5 to about 10 Hz) and modulated. CDRH's experience with EMI problems in other devices (e.g., apnea monitors) indicates that external electromagnetic signals, with amplitude modulation falling within the band-pass of the physiological signal being measured, would likely be where interactions would occur. Indeed, the IEC 60601-1-2 standard, the most prominent electromagnetic compatibility standard for medical electrical equipment, currently requires that radiated immunity testing be performed with exposure to a signal modulated within the most significant band-pass of the device or with a default modulation.[11] Therefore, potentially offending outside signals with modulation characteristics

close to the physiological signals being measured by a medical device are much more likely to interfere than other signals. This is not to say that medical devices exposed to electromagnetic fields with no low-frequency amplitude modulation would be immune to EMI. On the contrary, the in vitro results in the table clearly suggest that the swept RF EASS caused EMI in a small, but not insignificant, portion of devices.

FDA LETTER TO PHYSICIANS

Following the TEPRSSC meeting, CDRH sent a letter to cardiologists, neurologists, and other clinicians to provide basic information about concerns for medical device EMI from EASS and metal detectors, and offer a few suggestions intended to minimize risk. This letter contains a brief synopsis of the FDA MDR network incident reports relating to these interactions. The letter points out that the number of reported significant incidents is very low, and that CDRH is working with the device manufacturers and EASS and metal detector manufacturers to develop solutions. It also contains some simple precautions for patients who use electronic medical devices that may be exposed to EASS or metal detectors. Among these suggestions are:

- Be aware that EASS may be hidden and not readily visible.
- Avoid staying near an EASS or metal detector any longer than necessary; avoid leaning on these systems.
- If a security check with handheld metal detectors is required, alert the security personnel about any implanted or patient-connected medical device and request minimal exposure, or, if possible, an alternative form of search.

If any device malfunction is noted, users should make this known to their physician and/or the device manufacturer. In cases of serious interactions and health consequences, manufacturers must report such incidents to FDA. The device user or medical practitioner can also report the incident directly to FDA under the MedWatch program (telephone 800-FDA-1088).[12]

Harthorne and others have suggested that the brief time for normal passage through an EASS or metal detector gate

would tend to minimize the chances for clinically significant EMI with medical devices.[13] In many instances, this may well be the case, which could account for the relatively small number of reports considering the large volume of patients exposed to these systems. However, there are many situations where passage through the security system or exposure to hand-held detectors occurs over an extended time period. For example, delays at a busy airport security station may keep a person to the electromagnetic field longer than just a few seconds. Alternatively, security system configurations that place an EASS near a cashier or workstation are not uncommon. Such configurations appear likely to expose a person within the electromagnetic field for longer periods of time. In addition, exposures to the hand-held metal detectors are usually of short duration, but there are incident reports involving these products where the exposure appears to have been longer.

If time constraints for exposure to security systems is not always practical, then an understanding of the electromagnetic field characteristics around the EASS or metal detector could provide a predictor of the potential for EMI. A suggestion for this has been made by McIvor et al.[6] In their paper, calculations were made of the induced voltages onto a pacemaker lead system loop of 200 cm^2 using measurements of the electromagnetic fields of the EASS used in the study.

The paper explains that some of these induced voltage values calculated from EASS measurements fall outside the specifications for normal and defined pacemaker operation from the European pacemaker standard EN 50061/A1.[14] The result of some of the larger EASS induced voltages might, under circumstances such as the patient remaining in the EASS electromagnetic fields for an extended period of time, lead to pacemaker malfunction and possible patient risk.

Concern has also been noted because the emissions (carrier frequency or modulations) from different types of electronic security systems can fall within the physiological pass band of several kinds of ambulatory medical devices. However, the scarcity of public information about the characteristics of the electromagnetic fields emitted from

these systems makes it difficult to evaluate the potential susceptibility of medical devices to these fields.

ELECTROMAGNETIC FIELD MEASUREMENTS

Because of the paucity of information on the electromagnetic fields emitted by EASS, CDRH has measured these fields around a number of sample EASS (Figure 1 illustrates one of these measurements).[15] A summary of the results were presented at the TEPRSSC meeting. The CDRH measurements did not encompass all of the types of EASS, but did include the following:

- An extra-low-frequency (ELF) magnetic continuous wave (CW) system operating at 219 Hz.
- A voice-frequency magnetic CW system operating at 535.7 Hz.
- Three low-frequency pulsed magnetic systems operating at 58 KHz.
- Three frequency-modulated (FM) swept RF systems operating between 1.8 and 2.1 MHz or 7.2 and 9 MHz.

These measurements showed that the electromagnetic fields around the transmitting EASS pylon vary spatially from top to bottom, side to side, and going away from the pylon. The electromagnetic fields also vary depending on the specific system design and whether the EASS is used with pairs of pylons (transmitter and receiver) or a single pylon. For example, the measurements revealed that the single-pylon setup showed broader field strength patterns than the patterns around the paired pylons. In addition, measurements of the pulsed magnetic systems at a reference height of 130 cm, and a distance of 36 cm from the transmitter, revealed remarkably consistent field strengths of about 61–65 μT, even though one system was measured with the pylons separated more than 1 m further than the other systems. The highest fields were measured from the ELF magnetic EASS (122 μT), whereas the swept RF systems were measured at 1 μT or lower.

FUTURE DIRECTIONS

Unfortunately, only a few studies have been published on EASS and metal detector interference with a few critical de-

vices such as cardiac pacemakers and ICDs. These studies appear inconsistent about the significance of such interference. In addition, it is not clear whether the types of security systems used in the published studies represent the entire range of technologies in use (e.g., certain types of the lower-frequency magnetic field EASS typically used in libraries seem to be unrepresented). Thus, studies with broader objectives that cover the range of security systems need to be mounted to examine both the medical device susceptibility and the clinical relevance of any device-related EMI in terms of effects on the patient. Such an effort should include all potentially susceptible medical device classes, such as spinal cord stimulators, for a variety of malfunctions potentially due to EMI with security systems. Additionally, manufacturers of both the medical devices and the electromagnetic field source products (EASS and metal detectors) should work together to minimize the risk for EMI through better communications, design, and testing.

With the pace of technology and the cost factors relating to healthcare both increasing, it can be expected that ever-larger numbers of medical devices will become more complex, with more capabilities and increasing portability. It seems likely then that more medical devices will come into the proximity of EASS and metal detector systems. At the same time, the security industry is rapidly advancing, which is driving the need for consistent information about the electromagnetic fields generated by these systems. In addition, there is the need to develop voluntary medical device immunity standards and EASS and metal detector emission standards to address EMI among these products. Such standards should have consistent test methods reflective of the electromagnetic fields encountered by medical devices. These test methods should be reproducible using readily available and reasonably affordable instrumentation.

Physicians, patients, security system users, manufacturers, and the public all have a stake in obtaining and using the information about the potential for medical device EMI. Since medical devices span a wide range of functions and configurations, there is a great need to evaluate the potential for EMI in a range of devices. The most immediate concern

lies with the critical life-supporting and life-sustaining devices, such as cardiac pacemakers. However, other vital medical devices have been affected (e.g., implanted spinal cord stimulators) or could be affected (e.g., portable respirators, infusion pumps, and monitoring systems) by EMI when passing through an EASS system or metal detector.

CONCLUSIONS

With the information gathered by CDRH from MDR reports, clinical and technical literature, and laboratory measurements, there is basis for concern that the normal functioning of some medical devices may be interfered with by EASS or metal detectors. This concern is mitigated by the low numbers of documented cases of EMI in view of the estimated large numbers of exposures.

Although it is not considered a major public health problem at the moment, the potential serious health consequences for medical device users and the potential susceptibility of a number of vital medical devices warrant a cautious approach to examining the EMI between EASS and metal detectors and medical devices. EASS and metal detectors certainly benefit the public in an age of heightened security awareness, but this must be balanced with the potential for EMI with critical medical devices. Medical device manufacturers, EASS and metal detector manufacturers, and industry regulators must work together to formulate ways to address these EMI concerns so that device users, clinicians, and the public are not unduly alarmed. Voluntary performance standards and equipment labeling can play an important role in establishing medical device EMI immunity and setting reasonable limits on the electromagnetic source emissions from EASS and metal detectors.

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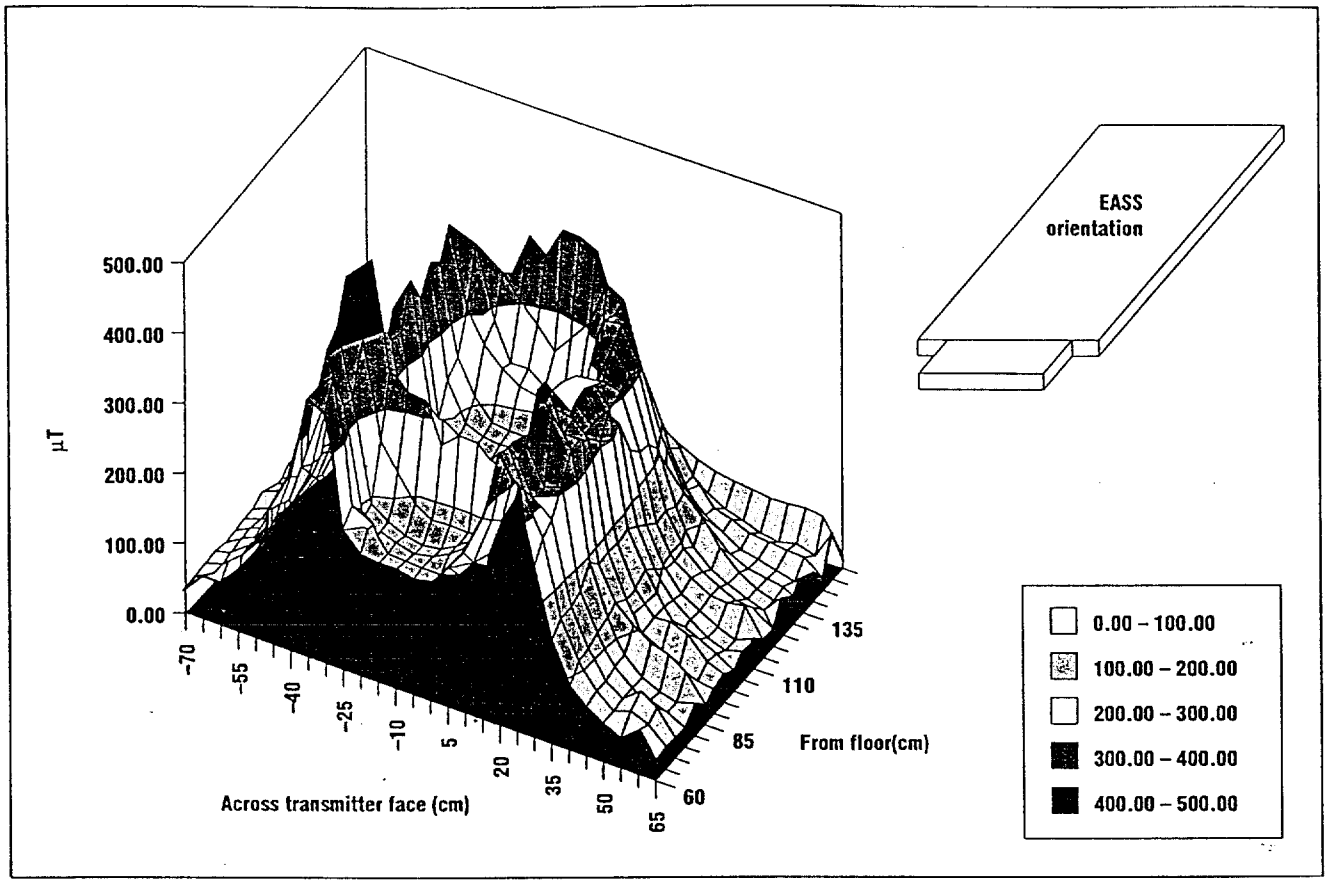

Figure 1. Measurement of the electromagnetic fields from a typical electronic article surveillance system. PM vertical plane 6 cm from transmitter pylon face. (From Engineering Characterization of Common Electronic Article Surveillance Systems Electromagnetic Fields *by Jon Casamento).*

Medical Device	Electronic Article Security System			
	Continuous Wave Magnetic	Pulsed Magnetic	Swept Radio Frequency	Microwave
Cardiac Pacemaker	54% (29/54)	44% (24/54)	12% (4/33)	0% (0/5)
Implanted Cardiac Defibrillator	0% (0/1)	0% (0/1)	1/M	1/M

Table I. In vitro EASS interactions with medical devices from published studies.